

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE NEW ENGLAND COMPOUNDING)
PHARMACY, INC. PRODUCTS LIABILITY)
LITIGATION)

MDL No. 2419
Dkt. No 1:13-md-2419 (RWZ)

THIS DOCUMENT RELATES TO:)

All Cases)

Memorandum in Support of
Motion to Compel Compliance with Subpoena to NECC

Defendants Saint Thomas Outpatient Neurosurgical Center, LLC; Howell Allen Clinic, a Professional Corporation; John Culclasure, MD; Debra Schamberg, RN, CNOR; Vaughan Allen, MD; Specialty Surgery Center, PLLC; Kenneth R. Lister, MD; Kenneth Lister, MD, PC; and Donald E. Jones, MD (collectively "Tennessee Clinic Defendants"), hereby move the Court, pursuant to Fed. R. Civ. P. 45, to compel the New England Compounding Center ("NECC") to comply with the subpoena for production of documents. In support of their motion, the Tennessee Clinic Defendants state as follows:

Background

The relevant procedural background is as follows:

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|----------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| April 17, 2015 | The Tennessee Clinic Defendants served NECC with a subpoena for documents and deposition testimony. |
| May 1, 2015 | The Trustee served responses and objections to the document requests. ¹ |
| May 1, 2015 | The Trustee filed a motion for a protective order seeking to avoid NECC's obligation to present a witness pursuant to Fed. R. Civ. P. 30(b)(6). ² |
| May 28, 2015 | Magistrate Judge Boal heard argument on the Trustee's motion for protective order. At the hearing, counsel for the Trustee represented to the Court that NECC had already produced the documents necessary to prove NECC's fault. ³ |
| June 18, 2015 | Out of nowhere, NECC produced more than 60,000 pages of <u>new</u> documents in response to a phantom request from the PSC, which has still never been seen by the Tennessee Clinic Defendants. In the email to the Tennessee Clinic Defendants notifying them of production of the documents, NECC described the documents as "related to" the Tennessee Clinic Defendants but gave no further information about the content of the production or explanation for why the documents had not been produced previously. |
| July 21, 2015 | The Tennessee Clinic Defendants sent a letter to NECC (1) requesting a meet and confer on document issues, (2) asking for an explanation regarding the 60,000 new documents produced on June 18, and (3) asking the Trustee to produce something to allow indexing of the 90,000+ pages produced by NECC. ⁴ |
| July 24, 2015 | The Tennessee Clinic Defendants again wrote the Trustee asking for some indexing of the relevant documents by Bates range and, again, requesting a meet and confer. ⁵ |

The Trustee refuses to participate in the meet and confer. Instead, the Trustee wants to wait until the Court rules on the choice-of-law briefing to discuss these issues.⁶ These

¹ NECC's responses, which contain the document requests, are attached as Exhibit 1.

² Dkt. 1810.

³ Hr'g Tr. 29:18-30:5 (May 28, 2015 hearing before Magistrate Judge Boal).

⁴ The letter is attached hereto as Exhibit 2.

⁵ The letter is attached hereto as Exhibit 3.

documents are relevant to these cases no matter what law applies and should have been produced by now.⁷ The Tennessee Clinic Defendants' only remaining option is to file this motion to compel.

Law and Argument

I. The Scope of Discovery

The scope of discovery is broad, and, as the United States Supreme Court has instructed, Fed. R. Civ. P. 26 must be "construed broadly to encompass any matter that bears on, or that reasonably could lead to other matters that could bear on, any issue that is or may be in the case."⁸ "As a general matter, relevancy must be broadly construed at the discovery stage, that is, information is discoverable if there is any possibility it might be relevant to the subject matter of the action. Relevant information includes any matter that is or may become an issue in the litigation."⁹

"[T]he party from whom discovery is sought has the burden of showing some sufficient reason why discovery should not be allowed, once it has been determined that the items sought are properly within the scope of Rule 26(b)."¹⁰

The documents sought by the subpoena at issue are plainly relevant and within the appropriate scope of discovery. They are not privileged, and the Trustee has failed to adequately explain why the documents have not been produced. Thus, NECC should be compelled to respond to the subpoena and produce the requested documents.

⁶ The email exchange between the Tennessee Clinic Defendants and the Trustee is attached hereto as Exhibit 4.

⁷ For example, many of the documents sought pertain to the recognized standard of acceptable professional practice applicable to the Tennessee Clinic Defendants and are relevant and discoverable regardless of which state's law applies to NECC's fault. *E.g.*, Request Nos. 4, 5, 6, 7, 9, 12, 13, 14.

⁸ *Oppenheimer Fund, Inc. v. Sanders*, 437 U.S. 340, 351 (1978).

⁹ *Whittingham v. Amherst College*, 164 FRD 124, 126-27 (D. Mass. 1995) (internal citations and quotations omitted).

¹⁰ *Kozlowski v. Sears, Roebuck & Co.*, 73 FRD 73, 76 (D. Mass. 1976) (internal citations omitted).

II. Overarching Issues

At the outset, it is necessary to apprise the Court of several practical problems that have arisen during the Tennessee Clinic Defendants' attempts to obtain discovery from NECC. It may be helpful to consider some of these broader issues before delving into disputes regarding specific document requests.

a. General Referral to Documents Produced on Repository

The Trustee prefaced the document responses with a "Preliminary Statement" which said "documents responsive to the Tennessee Clinic Defendants' Requests can be located in the US Legal Repository among the 32,000+ pages of documents NECC has already produced." To make matters worse, the Trustee subsequently produced another 60,000+ pages of documents in response to some sort of informal request from the PSC.

The Tennessee Clinic Defendants have tried to make focused requests for documents they need to defend these cases. The Trustee's response of, "see documents produced," sending the Tennessee Clinic Defendants to an unorganized, unindexed dump of nearly 100,000 documents is of no help.

The Tennessee Clinic Defendants were never even provided with the requests that prompted the last batch of 60,000 documents. No party should be allowed to "dump" masses of documents into a repository and claim that the dump satisfies specific document requests. This is plainly inappropriate.¹¹

¹¹ See *Monaghan v. SZS 33 Associates, L.P.*, 148 F.R.D. 500, 513 (S.D.N.Y. 1993) ("In light of Miller's statements regarding the existence and condition of more than 500,000 documents, it is unacceptable at this stage in these proceedings to impose upon the Plaintiffs what is ultimately SZS's burden, to wit, that of locating, identifying, and organizing its own documents. It is entirely unreasonable to subject the Plaintiffs to SZS's wandering haystacks of matter unorganized.")

As the First Circuit has observed:

At the very least, the defendants were entitled to responses or objections addressed to "each item or category [of items]." Fed. R. Civ. P. 34(b)(2)(B). The plaintiffs never supplied such an index, suggesting instead that the defendants find the needle in the haystack.¹²

Thus, regardless of the rulings on the specific document categories below, the Trustee should be compelled to provide (1) an index of the documents that have been produced (to allow for some categorization of what has been produced); (2) Bates ranges for documents that are responsive to the Tennessee Clinic Defendants' document requests (e.g., in response to Request No. ___, the Trustee should be ordered to say that responsive documents have been produced at pages Bates numbered _____); and (3) an index of any relevant document that have *not* been produced but are subject to pending document requests from the Tennessee Clinic Defendants.¹³

b. Missing Documents

At the April 10, 2014 hearing, when the Trustee agreed to make the documents produced to the PSC available to all parties, counsel for the Trustee represented to the Court that NECC had produced "43,000 or 44,000 pages of documents" to the PSC.¹⁴ However, as of the Trustee's May 1, 2015 response to the subpoena (over a year later), NECC had produced just under 33,000 pages of documents to parties other than the

¹² *Mulero-Abreu v. Puerto Rico Police Dept.*, 675 F. 3d 88, 93 (1st Cir. 2012)

¹³ It should be noted that the Plaintiffs know what categories of documents have and have not been produced because the Plaintiffs originally requested the documents. For example, the PSC presumably sent a request for all NECC standard operating procedures. In response, NECC likely sent an enclosure letter with the procedures that said (basically) "enclosed as Bates 100-200 are all NECC standard operating procedures." Relatedly, counsel for the Trustee stated in open court that there was a "lengthy meet and confer process" about the documents that would be produced to the PSC. Hr'g Tr. 27:14-22 (April 10, 2014 status conference). There must be some letter or memorandum reflecting an agreement on the documents that would and would not be produced as part of that process, and some sort of enclosure letter transmitting the documents. The Tennessee Clinic Defendants requested these document requests and responses from the PSC many months ago in the form of a request for production. It went unanswered and is now the subject of a motion to compel pending before the Court at Dkt. 1830.

¹⁴ Hr'g Tr. 27:14-29:7 (April 10, 2014 status conference).

PSC. The Tennessee Clinic Defendants asked the Trustee for an explanation as to why ~10,000 documents were produced to the PSC but withheld from other parties (given the Trustee's representations to the Court that the documents produced to the PSC would be made available to everyone), but the Trustee never responded.¹⁵

Likewise, there is a ~1,500-page gap in NECC's page numbering, indicating additional documents are missing from NECC's production.¹⁶ It is impossible to know whether there are an additional 1,500 pages produced to the PSC that the Tennessee Clinic Defendants do not have, and, more importantly, what these documents are. Presumably, these documents were produced to other parties at some point (otherwise, they would not have been Bates numbered), but they have been withheld from the document repository without explanation.

As the U.S. Supreme Court has observed, "[m]utual knowledge of all the relevant facts gathered by both parties is essential to proper litigation."¹⁷ The Court should order that any documents NECC has produced to some parties in this litigation must be produced to all parties in this litigation.¹⁸

¹⁵ Admittedly, the missing ~10,000 pages may have been included in the 60,000+ pages produced subsequently, but the Trustee has not indicated one way or another on this point. This is a perfect example of why serial "dumps" of documents achieves little in the way of pointed document discovery.

¹⁶ NECC_MDL000030271-31809.

¹⁷ *Hickman v. Taylor*, 329 U.S. 495, 507 (1947).

¹⁸ To the extent the documents were produced during mediation, this does not confer a privilege upon documents that are not otherwise privileged. See *Sheldone v. Pennsylvania Tpk. Comm'n*, 104 F. Supp. 2d 511, 515 (W.D. Pa. 2000), *aff'd* (Aug. 8, 2000) (internal citations omitted).

III. Specific Document Requests¹⁹

NECC's responses to the document requests contain mostly boilerplate objections. Rather than addressing every boilerplate objection for each document request, the Tennessee Clinic Defendants have tried to focus on what appears to be the Trustee's "real" objection(s) to each request.²⁰ The Trustee should be ordered to produce the below categories of plainly-relevant documents:

Request 1: Personnel Files

Request No. 1 requests the personnel files for (1) NECC's owners or former employees who have been indicted and (2) the individuals involved in the manufacture or compounding of the three contaminated lots of MPA. The Trustee objected, arguing that the personnel files are irrelevant and confidential. These objections are without merit.

The personnel files sought are relevant for a variety of purposes:

- Personnel files likely contain information about the employee's training, which is at issue in the allegations of fault pertaining to NECC.²¹
- Personnel files may contain complaints about employee misconduct, including misconduct by the pharmacists or technicians involved in compounding the MPA at issue. This information is certainly relevant to NECC's fault as it would prove that NECC was on notice of its employees' wrongful actions but failed to take appropriate remedial action.
- Personnel files likely contain contact information that will enable the Tennessee Clinic Defendants to locate and contact former employees.²²

¹⁹ Some of these topics better lend themselves to deposition testimony. The Tennessee Clinic Defendants have narrowed the document requests as much as possible, but, in light of the Court's order at Dkt. 2123 prohibiting the Tennessee Clinic Defendants from deposing NECC, the document requests are the only means the Tennessee Clinic Defendants can pursue to try to establish these facts for trial. If the Court grants the Tennessee Clinic Defendants' motion to reconsider at Dkt. 2185 and permits the Tennessee Clinic Defendants a deposition of NECC on a greatly-narrowed subset of topics, some of these document requests may be rendered moot.

²⁰ Obviously, a meet and confer would have been helpful in this endeavor, but the Trustee refused.

²¹ STOPNC Master Answer at 70 [Dkt. 1455].

These files certainly fall within the broad scope of discovery.

Next, the Trustee claims that these files are *per se* confidential, without explaining why or identifying the type of information within the files that is sensitive. In short, the Trustee has failed to carry his burden of establishing that these files should not be produced.

Regardless, there is a robust protective order in place which permits the Trustee to designate sensitive portions of the personnel files as confidential.²³ Additionally, the Tennessee Clinic Defendants have proposed that the Trustee simply redact any truly sensitive information from the personnel files, such as information about a former employee's health problems. The Trustee never responded to this proposal.

Requests 4, 5, and 6: Documents Regarding the Tennessee Clinic Defendants

Requests Nos. 4, 5, and 6 seek NECC's customer files regarding the Tennessee Clinic Defendants and any communications in NECC's possession with or about the Tennessee Clinic Defendants. It is beyond frustrating that, on the brink of expert disclosures, the Tennessee Clinic Defendants still cannot get a straight answer about what communications NECC had with or about the Tennessee Clinic Defendants.

The Trustee responded that the requests were "too broad to conduct a reasonable search for responsive documents" but offered to meet and confer (and now refuses to do so). In response, the Tennessee Clinic Defendants offered to limit the

²² The Tennessee Clinic Defendants asked the Trustee whether he would produce several former NECC employees for depositions. The Trustee never responded. And, despite repeated requests, the Trustee has yet to identify ANY effort made to contact former employees to serve as witnesses in this case. The Tennessee Clinic Defendants are willing to take this burden upon themselves but cannot do so without addresses and phone numbers for the witnesses.

²³ 3rd Am. Prot. Order [Dkt. 814].

requests to the years 2011 and 2012 and offered to propose search terms to identify relevant documents. The Trustee did not respond to either proposal.

The document requests themselves are not facially overbroad. They are limited to three specific clinics from Tennessee that purchased from NECC.²⁴ And, there appears to be no dispute that these documents are relevant and discoverable. There is no reason they should not be produced.

Request 7: Customer Site Visits or Inspections

Request No. 7 asks NECC to produce documents related to customer site visits or inspections of NECC's facility. The precise nature of NECC's objection to this request is unclear. The Tennessee Clinic Defendants should not be required to decipher it, particularly when the documents are obviously discoverable.

The Plaintiffs allege that the standard of acceptable professional practice required the Tennessee Clinic Defendants to conduct a site visit or inspection of NECC prior to purchasing.²⁵ ²⁶ The Tennessee Clinic Defendants are simply trying to determine (1) how many of NECC's thousands of customers actually conducted such a site visit and (2) what the results of any site visits were.²⁷ If the vast majority of health care providers were not performing site visits or inspections in 2012, it could not have been standard practice. Further, if NECC passed all audits or inspections undertaken by customers, NECC probably would have passed such an audit conducted by the

²⁴ STOPNC, SSC, and PCA Pain Care Center, Oak Ridge, where Donald Jones, MD was employed.

²⁵ 2nd Am. Master Compl. ¶ 192 [Dkt. 1719].

²⁶ Tennessee's Health Care Liability Act, which applies to the Plaintiffs' claims, requires proof of a departure from the "recognized standard of acceptable professional practice" and proof that the departure caused the Plaintiffs' injuries. TENN. CODE ANN. § 29-26-115.

²⁷ Thus far, the Tennessee Clinic Defendants have only been able to identify two NECC customers (of the thousands) who actually conducted such a site visit. NECC "passed" both inspections.

Tennessee Clinic Defendants. Thus, the information sought by this request is plainly relevant and discoverable.

Requests 9 and 14: Patient-Specific Prescriptions

Request No. 9 seeks documents related to whether customers were required to send patient-specific prescriptions or a list of patient names when submitting orders to NECC. There seems to be no dispute that these documents are relevant and discoverable since the PSC claims that the Tennessee Clinic Defendants' failure to use patient-specific prescriptions somehow caused the Plaintiffs' injuries.

The Trustee objects to the request, claiming that the request "is too broad to conduct a reasonable search for responsive documents." But, then, the Trustee goes on to identify some responsive documents (18 pages) that NECC already produced. Thus, apparently, the Trustee was able to conduct a search of the documents that have already been produced to identify responsive documents. Presumably, the Trustee can conduct a similar search of the documents that have NOT been produced.

The documents are relevant and should be produced.

Similarly, Request No. 14 seeks 2011 and 2012 order forms for some well-respected NECC customers. The Trustee objected to disclosing information about NECC's "Business Associates" without explaining why he believes the documents are privileged from discovery (it is difficult to conceive of an applicable privilege justifying the objection; there is obviously no "business associate" privilege, and NECC is no longer operating), and the Trustee also raised an objection under HIPAA, despite the near-certain absence of protected personal health information.

These documents are relevant and necessary to rebut the Plaintiffs' claim that the Tennessee Clinic Defendants "knew, or should have known, that NECC was not registered to distribute prescription drugs wholesale in their state."²⁸ If dozens of well-known and well-respected health care facilities in the country purchased medication from NECC the same way the Tennessee Clinic Defendants did, it strains credibility to argue that the standard practice was otherwise.

Requests 12 and 13: Due Diligence Conducted by Other Customers

Request No. 12 seeks documents regarding due diligence other NECC customers or potential customers conducted before purchasing from NECC. The Trustee objected to this request on the grounds that it is too broad to conduct a reasonable search. Request No. 13 is essentially a focused version of Request No. 12 and seeks documents related to due diligence performed by a specific subset of well-known customers of NECC. NECC's primary objection to Request No. 13 appears to be that responding would require NECC to provide information about NECC's "Business Associates."

Request No. 12 tracks the topics that the Plaintiffs contend the Tennessee Clinic Defendants should have asked NECC about prior to purchasing (*i.e.*, the "due diligence" that the Plaintiffs allege was required prior to purchasing).²⁹ If other customers pursued these areas of inquiry with NECC, NECC's responses to these inquiries are relevant because NECC likely would have provided the same information if the Tennessee Clinic Defendants had asked the same or similar questions.

²⁸ 2nd Am. Master Compl. ¶ 171 [Dkt. 1719].

²⁹ See 2nd Am. Master Compl. ¶ 234 [Dkt. 1719].

What level of due diligence other well-known NECC customers in Tennessee and across the country (identified in Request No. 13) conducted before buying from NECC is relevant to determining the standard of practice for pre-purchase due diligence. If the most sophisticated health care facilities in Tennessee and across the country were conducting the same amount of due diligence as the Tennessee Clinic Defendants prior to purchasing from NECC, that is certainly relevant (and persuasive) for the jury in evaluating the conduct of the Tennessee Clinic Defendants.

These documents are relevant; the requests are narrowly tailored; and there is no applicable privilege. There is no reason these documents should not be produced. Notwithstanding the fact that this information is plainly relevant and discoverable, the Tennessee Clinic Defendants are willing to withdraw Request No. 12 if NECC will respond to Request No. 13 without further delay.

Requests 16, 17, and 18: Cleaning, Testing, and Autoclave Records

Request Nos. 16, 17, and 18 seek records from NECC regarding (1) cleaning of the cleanroom, (2) testing of the cleanroom, and (3) autoclave records. The Trustee identified some documents that were already produced, but the documents identified are only partially responsive to the requests.

For example, the cleaning records identified by the Trustee only pertain to the monthly cleanings performed by UniFirst. Both USP 797 and NECC's own internal policies and procedures required cleanings much more frequently than the monthly cleanings performed by UniFirst. These records are critical to determining whether NECC was properly maintaining the facility, and they should be produced.

Likewise, the Trustee identified some air and surface testing results for 2012 that were produced. But, the request sought testing results from 2010-2012, and the Trustee would not even confirm whether or not all 2012 results had been produced.

Conclusion

For the foregoing reasons, the Tennessee Clinic Defendants respectfully request that the Court enter an order requiring NECC to:

1. Produce an index for the documents produced to date that allows for some categorization of the serial NECC “document dumps”
2. Produce an index of documents not-yet-produced (or withheld on a claim of privilege)
3. Provide an explanation for the 10,000 documents apparently provided to the PSC but not provided to the Tennessee Clinic Defendants
4. Provide an explanation for the 1,500-page gap in the Bates numbering of the documents produced
5. Produce (indexed) any documents NECC has provided to other parties but not the Tennessee Clinic Defendants
6. Produce (or identify by Bates number if already produced) documents responsive to:
 - a. Request No. 1 (personnel files)
 - b. Request Nos. 4-6 (NECC documents specific to the Tennessee Clinic Defendants)
 - c. Request No. 7 (documents related to customer site visits or inspections)
 - d. Request Nos. 9 and 14 (documents regarding patient-specific prescriptions)
 - e. Request Nos. 12 and 13 (documents regarding due diligence conducted by other customers)
 - f. Request Nos. 16-18 (cleaning, testing, and autoclave records).

Oral Argument

The Tennessee Clinic Defendants believe that oral argument on this motion is unnecessary given (1) the tight discovery deadlines in this case, (2) the straightforward nature of the motion, and (3) the Trustee and the PSC's oft-stated desire to preserve the assets of the estate for NECC's victims. Foregoing oral argument will obviate the need for the Trustee and/or his counsel to prepare for and attend a hearing, as they can rely on a written response. Of course, if the Court would like to hear oral argument, the Tennessee Clinic Defendants are pleased to oblige and respectfully suggest that the motion be heard at the hearing before Magistrate Judge Boal on September 9, 2015, at 3:30 pm EDT in Courtroom 14.³⁰

Respectfully submitted,

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* Admitted pursuant to MDL Order No. 1.

** Admitted *pro hac vice*.

³⁰ The Tennessee Clinic Defendants believe that this motion has been referred to Magistrate Judge Boal pursuant to Dkt. 1708, which referred all "discovery motions" to Magistrate Judge Boal. If this motion is not referred to Magistrate Judge Boal, the Tennessee Clinic Defendants request oral argument at the status conference before Judge Zobel on September 10, 2015, at 2:00 pm EDT in Courtroom 12.

CERTIFICATE OF SERVICE

I hereby certify that this document filed through the CM/ECF system will be served electronically to the registered participants identified on the Notice of Electronic Filing and copies will be e-mailed or mailed via regular U.S. mail to those participants identified as unregistered this 25th day of August, 2015.

/s/ Chris J. Tardio

Chris J. Tardio